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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,137

02/25/2008

Neil Berinstein

API-03-03-PCT-US

1779

65626 7590 08/26/2010  
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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

08/26/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,137	<b>Applicant(s)</b> BERINSTEIN ET AL.	
	<b>Examiner</b> Jeffrey E. Russel	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2010 and 15 June 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 67, 69 and 73-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 73-78 is/are allowed.
- 6) ☒ Claim(s) 67 and 69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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1. Applicant's election with traverse of the invention of Group II and the species LMDMQTFKA (SEQ ID NO:7) in the reply filed on January 7, 2009 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

The elected species has been examined and determined to be novel and unobvious over the prior art of record or any combination thereof. Search and examination has been extended to include the species SEQ ID NOS:8, 9, 11, 12, 21, 24, 29, 30, 32, and 34.

2. The Sequence Listing filed July 29, 2010 is approved.

3. Instant claims 67, 69, and 73-78 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/462,945 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 67 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 01/47959. The WO Patent Application '959 teaches Applicants' peptides which are designated SEQ ID NOS:21, 24, 29, 30, 32, and 34. See page 25, line 19; page 26, line 2; page 24, last line; page 25, line 12; page 25, line 1; and page 25, line 2; respectively, of the WO Patent Application '959. The peptides are assayed in a live cell assay in the presence of culture medium, the aqueous portion of which corresponds to Applicants' pharmaceutically acceptable carrier. The peptides also can be included as part of an immunogenic cocktail composition. See, e.g., the paragraph bridging pages 26 and 27, and the paragraph bridging pages 28 and 29. In view of the similarity in amino acid sequence and utility between the peptides of the WO Patent Application '959 and Applicants' claimed peptides, inherently the

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peptides of the WO Patent Application '959 will be immunogenic as determined by ELISPOT analysis of human T-cell cultures or human T cell cytotoxicity assay to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the WO Patent Application '959 and Applicants' claimed invention to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than the WO Patent Application '959.

6. Applicant's arguments filed June 15, 2010 have been fully considered but they are not persuasive.

In their Remarks (see, e.g., the sentence bridging pages 11 and 12), Applicants have clearly stated that the claim language is to be interpreted as closed language, i.e. as not permitting any additions, deletions, or modifications to the recited sequences. Accordingly, the rejection under 35 U.S.C. 112, second paragraph, addressing this issue is withdrawn; the anticipation rejection under 35 U.S.C. 102(b) based upon the WO Patent Application 01/47959 and directed to the species SEQ ID NO:7 is withdrawn; and the anticipation rejection based upon Jager et al (U.S. Patent No. 6,911,529) is withdrawn.

Berinstein et al (U.S. Patent Application Publication 2005/0112099) is cited as art of interest. However, the reference is not prior art against the instant claims (see especially section 3 above), and the application upon which the reference is based, serial no. 10/825,026, is abandoned.

The WO Patent Application 2004/104039 is cited as art of interest. However, the reference is not prior art against the instant claims (see especially section 3 above).

7. Claims 73-78 are allowed.

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The species of claims 67 and 69 wherein the peptide is selected from one of SEQ ID NOS:8, 9, 11, and 12 are also novel and unobvious over the prior art of record or any combination thereof.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications

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such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/  
Primary Examiner, Art Unit 1654

JRussel  
August 25, 2010